K122313

stryker

Craniomaxillofacial

510(k) Summary

OCT 3 1 2012

Date prepared:	July 31, 2012
Submitter:	Stryker Craniomaxillofacial 750 Trade Center Way Portage, MI 49002 USA
Contact:	Rob Yamashita Phone: (269) 389-4258 / Fax: (269) 329-2235 rob.yamashita@stryker.com
Proprietary Name:	Stryker Universal SMARTLock Hybrid MMF System
Common Name:	Universal Hybrid MMF
Proposed Regulatory Class:	Class II
Product Codes:	DZL – Intraosseous fixation screw or wire JEY – Bone Plate
Predicate Device:	Stryker MMF Screw – K050535 KLS Martin Erich Arch Bar – K061271

Intended Use:

The Stryker Universal SMARTLock Hybrid MMF System is intended to be used for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during fracture healing.

Indication for Use:

The Stryker Universal SMARTLock Hybrid MMF System is indicated for the treatment of mandibular and maxillary fractures in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

Device Description:

The Stryker Universal SMARTLock Hybrid MMF System is a maxillomandibular fixation system that consists of a pure titanium fixation Plate, 2 self-drilling locking Screws made out of titanium alloy (6mm and 8mm), a bending instrument and a spacing instrument. These devices are stored in a dedicated module and in a dedicated generic instrument tray, respectively. Both the tray and the module are stored in a generic storage container.

The Plate has in-plane bendable attachment loops for screw fixation on either the maxilla or mandible. The fixation loops can be bent with the Bender. The locking screw fixation together with use of the Spacer is designed to prevent pressure on the gingiva from the fixated Plate.

Technological Characteristics:

The Stryker Universal SMARTLock Hybrid MMF System is similar to its Predicate Devices in the following technological characteristics:

• Material:	The Stryker Universal SMARTLock Hybrid HMMF System is made of either commercially pure titanium or titanium alloy. The Predicate Devices are made of stainless steel.
• Design:	The Stryker Universal SMARTLock Hybrid MMF System is a combination of the legally marketed MMF Screw System (K050535) and Erich Arch Bar (K061271).
• Mode of Fixation:	Inter-radicular Screw Fixation or Circumferential wiring of dentures or teeth as with the Predicate Devices (K050535, K061271).
• Intermaxillary Stabilization:	With ligature wires as with the Predicate Devices (K050535, K061271).
• Packaging:	The devices of the Stryker Universal SMARTLock Hybrid MMF System are delivered non-sterile as are the Predicate Devices.

Clinical Testing:

No clinical testing was performed to support this submission.

Non-Clinical Testing:

The Stryker Universal SMARTLock Hybrid MMF System proved to be successful in all the tests conducted with regards to biocompatibility, cleaning, screw insertion, corrosion resistance, mechanical stability of construct, locking test, a system handling test and an end-user (cadaver) test.

Substantial Equivalence to Predicate Devices:

The Stryker Universal SMARTLock Hybrid MMF System combines the principles of operation of the Predicate Devices. It has nearly identical intended use and indications. Material and technological characteristics are similar to the legally marketed Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 31 2012

Stryker®
Craniomaxillofacial
Mr. Rob Yamashita
Associate Manager, Regulatory
750 Trade Centre Way, Suite 200
Portage, Michigan 49002

Re: K122313
Trade/Device Name: Stryker Universal SMART Lock Hybrid MMF System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, DZL
Dated: July 19, 2012
Received: August 2, 2012

Dear Mr. Yamashita:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122313

Device Name: Stryker Universal SMARTLock Hybrid MMF System

Indications For Use: The Stryker Universal SMARTLock Hybrid MMF System is intended to be used for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during fracture healing.
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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